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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/621,054

07/15/2003

Jan K. Caers

17595 (BOT)

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09/05/2007

EXAMINER

ANDERSON, CATHARINE L

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/621,054

Applicant(s)

CAERS ET AL.

Examiner

C. Lynne Anderson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 14, 15, 17-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 14, 15, 17-23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 December 2006 has been entered.

Response to Arguments

Applicant's arguments filed 15 December 2006 have been fully considered but they are not persuasive.

In response to the applicant's argument that Gardiner does not disclose the uniform spacing between the first plurality of perforations being different from the uniform spacing between the second plurality of perforations, it is noted that Gardiner does disclose different spacing within the first and second pluralities of perforations. In the first plurality of perforations, the perforations labeled Mon and Thur, and Tue and Wed, are uniformly spaced by a distance larger than the distance between the perforations in the second plurality of perforations, as shown in figure 5. Further, it is noted that the present claims merely disclose the uniform spacings being different, and does not clearly claim that the distances between the perforations in the first plurality are different than the distances between the perforations in the second plurality.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case, the examiner's interpretation of Whitmore does not involve hindsight reasoning because no conclusion of obviousness is being made. Whitmore is considered by the examiner to anticipate the claimed invention without the need for any obvious modifications. The examiner has applied the claimed limitations to the invention of Whitmore by defining first and second pluralities of perforations based on the device disclosed by Whitmore. Whitmore discloses a device comprising a plurality of perforations that fulfills the limitations of the claims. While Whitmore does not define the first and second pluralities of perforations, dividing the perforations shown by Whitmore into first and second regions does not require any modification of the disclosure of Whitmore and therefore does not involve hindsight reasoning.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "bore" in claim 8 is used by the claim and further defined to have a first end having a diameter greater than the diameter of a second end (i.e. having a conical shape), while the accepted meaning is "cylindrical." The term is indefinite because the specification does not clearly redefine the term. For purposes of examination, the claimed "bore" will be considered to have a cylindrical shape.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (4,228,796).

Gardiner discloses a device 10, as shown in figure 1, comprising a material 12 with an upper face, a lower face, and a plurality of perforations extending completely

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through the material. The plurality of perforations are comprised in non-overlapping first and second plurality of perforations, as shown in figure 5, the first plurality comprising the four perforations labeled Mon, Tue, Wed, and Thurs, and the second plurality comprising the three perforations labeled Fri, Sat, and Sun. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claims 2 and 8, the material 12 has an exterior border that is not perforated, as shown in figure 5.

With respect to claims 3 and 9, the material 12 is flexible to that the exterior border is in contact with a dermal area during use, as shown in figure 5.

Claims 1-2, 6-7, 12-13, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitmore, III et al. (6,036,632).

Whitmore discloses a device 10, as shown in figure 1, comprising a material 14 with an upper face, a lower face, and a plurality of perforations 12 extending completely through the material. A first group of perforations, the columns, are spaced apart by a first uniform distance. A second group of perforations, the rows, are spaced apart by a second uniform distance that is not equal to the first. The first and second plurality may be defined as a portion of one row and a portion of a column such that the first and second plurality do not overlap. The device is for assisting in making injections, and therefore is fully capable of being used to assist hyperhydrosis therapy.

With respect to claim 2, the material 14 has an exterior border that is not perforated, as shown in figure 1.

With respect to claims 6-7 and 12-13, the perforations have a first end opening at the upper face and a second end opening at the lower face, wherein the diameter of the first opening is greater than the diameter of the second end, as shown in figure 4.

With respect to claims 22-24, the distance between the perforations is 0.5 cm, as disclosed in column 1, line 47.

With respect to claims 25-26, the perforations have a conical shape, as shown in figure 5, and therefore the cross section of the perforations can be drawn as two non-parallel lines.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 2002/0086036) in view of Gardiner (4,228,796).

Walker discloses all aspects of the claimed invention with the exception of the use of a device having a plurality of perforations. Walker discloses in paragraphs [0087]-[0088] a method for assisting in hyperhydrosis therapy comprising determining a dermal area of a patient which exhibits hyperhydrosis by use of an iodine starch test, marking the area to be treated, and injecting botulinum toxin at the location of the mark.

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Gardiner teaches the use of a device comprising a material having an upper face, a lower face, and a plurality of perforations to assist in marking a dermal area to be given multiple injections, as disclosed in column 40-43. The device allows the user to mark areas that need to be injected and identify areas that have already been injected, as disclosed in column 1, lines 29-39.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to employ the device of Gardiner in the method for assisting hyperhydrosis therapy of Walker to allow for the marking of areas that need to be injected and identification of areas that have already been injected.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 02/068028 and GB 2 202 445 disclose devices for locating injection sites on a body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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March 2, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

